

In the Claims:

Please cancel Claims 1-44 without prejudice and add new Claims 45-88, such that the claims are as set forth below.

1-44. (Cancelled)

45. (New) A device for determining the concentration of an analyte in a biological fluid from a patient, comprising:

a piercing member sufficient to cause the fluid to flow from a site on the patient;

a sensor sufficient to generate an electrical signal indicative of the concentration of the analyte in the fluid, the sensor comprising: a working electrode; a sensing layer; a counter electrode; and a measurement zone sized to contain a volume of less than about 1 μ l; and
an analyzer operatively connected to the sensor.

46. (New) The device of claim 45, wherein the piercing member is a lancet.

47. (New) The device of claim 45, wherein the sensing layer comprises at least one agent sufficient for transferring electrons between the working electrode and the analyte.

48. (New) The device of claim 47, wherein the at least one agent comprises a redox mediator and/or an enzyme.

49. (New) The device of claim 47, wherein the at least one agent comprises an enzyme selected from a lactase oxidase, a glucose oxidase, and a glucose dehydrogenase.

50. (New) The device of claim 45, wherein the measurement zone is sized to contain a volume of less than about 0.5 μ l.

51. (New) The device of claim 45, wherein the sensor comprises a strip.

52. (New) The device of claim 45, wherein the working electrode is on a first substrate and the counter electrode is on a second substrate.

53. (New) The device of claim 45, wherein the working electrode and the counter electrode are coplanar.

54. (New) The device of claim 45, wherein the sensor further comprises a third electrode.

55. (New) The device of claim 45, the sensor being such that the signal generated by the sensor in connection with electrolysis of a buffer solution having a 10 mM concentration of the analyte is at least about nine times greater than the signal generated by the sensor in connection with electrolysis of the buffer solution absent the analyte.

56. (New) The device of claim 45, further comprising a sorbent material for transporting the fluid from the site to the sensor.

57. (New) The device of claim 56, wherein at least a portion of the sorbent material is disposed in the measurement zone.

58. (New) The device of claim 45, further comprising means for transporting the fluid from the site to the sensor.

59. (New) The device of claim 58, wherein the means for transporting comprises vacuum-producing means.

60. (New) The device of claim 58, wherein the means for transporting comprises pressure application, vacuum creation, capillary action, and/or wicking action.

61. (New) The device of claim 45, wherein the analyzer comprises an amperometric analyzer.

62. (New) The device of claim 45, wherein the analyzer comprises a coulometric analyzer.

63. (New) The device of claim 45, wherein the fluid is selected from blood, interstitial fluid, dermal fluid, sweat, and tears.

64. (New) The device of claim 45, wherein the analyte is selected from lactate and glucose.

65. (New) The device of claim 45, wherein at least two components selected from the piercing member, the sensor, and the analyzer form an integrated unit.

66. (New) The device of claim 65, wherein the sensor is detachable from the integrated unit.

67. (New) A device for determining a concentration of an analyte in a fluid from a site on a subject, comprising:

a piercing member sufficient to pierce the site such that the fluid flows therefrom; and
a sensor sufficient to generate a signal indicative of the concentration of the analyte in the fluid, the sensor comprising: a working electrode; a sensing layer; a counter electrode; and a measurement zone sized to contain a volume of less than about 1 μ l;

wherein the sensor is adapted so that a signal generated by the sensor in connection with electrolysis of a buffer solution with 10 mM glucose is greater than a signal generated by the sensor in connection with electrolysis of a buffer solution with no glucose.

68. (New) The device of claim 67, wherein the sensor is adapted so that a signal generated by the sensor in connection with electrolysis of a buffer solution with 10 mM glucose is about nine times greater than a signal generated by the sensor in connection with electrolysis of a buffer solution with no glucose.

69. (New) The device of claim 67, further comprising an analyzer operatively associated with the sensor.

70. (New) A method for determining the concentration of an analyte in a fluid from a site on a subject, the method comprising:

providing a piercing member, a sensor for generating a signal, and an analyzer for measuring the signal, wherein the sensor comprises: a working electrode; a sensing layer; a counter electrode; and a measurement zone;

piercing the site via the piercing member such that fluid flows from the site to the measurement zone;

generating a signal indicative of the concentration of the analyte in the fluid using less than about 1 μl of the fluid in the measurement zone via the sensor; and

measuring the signal via the analyzer.

71. (New) The method of claim 70, wherein the piercing member comprises a lancet.

72. (New) The method of claim 70, wherein the sensing layer comprises at least one agent sufficient for transferring electrons between the working electrode and the analyte.

73. (New) The method of claim 72, wherein the at least one agent comprises a redox mediator and/or an enzyme.

74. (New) The method of claim 72, wherein the at least one agent comprises an enzyme selected from a lactase oxidase, a glucose oxidase, and a glucose dehydrogenase.

75. (New) The method of claim 70, wherein the signal is generated using no more than about 0.5 μl of the fluid in the measurement zone.

76. (New) The method of claim 70, wherein the working electrode is on a first substrate and the counter electrode is on a second substrate.

77. (New) The method of claim 70, wherein the sensor further comprises a third electrode.

78. (New) The method of claim 70, the sensor being such that the signal generated by the sensor in connection with electrolysis of a buffer solution having a 10 mM

concentration of the analyte is at least about nine times greater than the signal generated by the sensor in connection with electrolysis of the buffer solution absent the analyte.

79. (New) The method of claim 70, further comprising transporting the fluid from the site to the measurement zone via a sorbent material.

80. (New) The method of claim 79, wherein at least a portion of the sorbent material is disposed in the measurement zone.

81. (New) The method of claim 70, further comprising, before said measuring, providing a vacuum at or around the site.

82. (New) The method of claim 70, further comprising transporting the fluid from the site to the measurement zone via vacuum, pressure, capillary action, and/or wicking action.

83. (New) The method of claim 70, wherein said measuring comprises amperometrically measuring.

84. (New) The method of claim 70, wherein said measuring comprises coulometrically measuring.

85. (New) The method of claim 70, wherein the fluid is selected from blood, interstitial fluid, dermal fluid, sweat, and tears.

86. (New) The method of claim 70, wherein the analyte is selected from lactate and glucose.

87. (New) The method of claim 70, wherein the site is located on an arm of the subject.

88. (New) The method of claim 70, wherein at least two components selected from the piercing member, the sensor, and the analyzer form an integrated unit.